

# **EXHIBIT 7**

4/12/2006 DALTON, Mary V.1

**THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

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**In Re: PHARMACEUTICAL ) MDL DOCKET NO.  
INDUSTRY AVERAGE WHOLESALE ) CIVIL ACTION  
PRICE LITIGATION ) 01CV12257-PBS**

**-----X**

**THIS DOCUMENT RELATES TO: )  
ALL ACTIONS )**

**-----X**

**Taken at 33 South Last Chance Gulch  
Helena, Montana  
Wednesday, April 12, 2006 - 8:43 a.m.**

**TELEPHONE DEPOSITION OF  
MARY DALTON**

**Reported by Mary R. Sullivan, RPR, RMR, Freelance  
Court Reporter and Notary Public, State of Montana,  
residing in Missoula, Montana.**

4/12/2006 DALTON, Mary V.1

1       **A. The State had the authority to do it**  
2       **within the guidelines that were available to the**  
3       **states under the federal participation and Medicaid**  
4       **program.**

5       **Q. And Montana Medicaid controlled that**  
6       **through the administrative rule-making process?**

7       **A. That would be correct.**

8       **Q. The legislature of Montana didn't need to**  
9       **be involved?**

10       **A. The legislature grants the--how would I**  
11       **say it. A state agency has no rule-making authority**  
12       **that is not granted to it by the state legislature.**

13       **Q. So state of Montana Medicaid controlled**  
14       **the reimbursement rate through the administrative**  
15       **rule-making process created by the state**  
16       **legislature?**

17       **A. State legislature gives the state agency**  
18       **the power to do administrative rules, and they--if**  
19       **you look back in the Montana Code Annotated, it will**  
20       **tell you what agencies have the power to do, rules**  
21       **and what areas.**

22       **Q. If Montana had wanted to reimburse**

4/12/2006 DALTON, Mary V.1

1     **pharmacies and physician providers based on actual**  
2     **acquisition costs, how would it do so?**

3     **A. I'm not an expert in pharmacy**  
4     **reimbursement.**

5     **Q. While you were there at Montana Medicaid--**  
6     **well, you're still there, but while you were the**  
7     **bureau chief, who were the pharmacy reimbursement**  
8     **experts?**

9     **A. The pharmacy program officers and the**  
10    **supervisors would have had more knowledge of this**  
11    **than I would have had.**

12    **Q. So that would be Dorothy Poulsen, Shannon**  
13    **Marr, Jeff Ireland and Terry Krantz?**

14    **A. Those are the people I recall. There**  
15    **could be additional people over a--I was there from**  
16    **1986 through 2001, so.**

17    **MS. O'SULLIVAN: Why don't we go off the**  
18    **record and take a short break.**

19    **THE DEPONENT: Good. You're going to have**  
20    **to find me a different chair.**

21    **(Whereupon, the deposition was in**  
22    **recess at 10:15 a.m., and subsequently reconvened at**

4/12/2006 DALTON, Mary V.1

1 Q. If it was a performance review of the drug  
2 delivery system for Montana Medicaid done in  
3 September 1996, that would have been under your  
4 supervisory duties as bureau chief?

5 A. It would have been.

6 Q. I'd like you to also look to Page 80. In  
7 about the middle of the page, the second full  
8 paragraph where it states, "The Department's No. 1  
9 funding priority in the 2003 biennium was for rate  
10 increases for Medicaid providers." Do you recall  
11 that that was the department's No. 1 funding  
12 priority?

13 A. I don't recall.

14 Q. The next sentence goes on to say, "This  
15 conflicts with their first alternative for  
16 controlling expenditures. DPHHS staff indicated  
17 adjusting provider service rates as the primary  
18 alternative for controlling Medicaid expenditures."  
19 Do you remember such a conflict?

20 A. I'm sorry, Katie, I'm not understanding  
21 what your question is to me.

22 Q. Okay. Sure. Let me try again.

4/12/2006 DALTON, Mary V.1

1       A. Okay.

2       Q. The first sentence said the No. 1 funding  
3 priority was to increase rates.

4       A. Okay.

5       Q. And then the audit says this conflicts  
6 with the first alternative for controlling  
7 expenditures, which is to adjust provider service  
8 rates. Do you remember any type of conflict between  
9 on the one hand DPHHS wanting to increase providers'  
10 reimbursement or rates and on the other hand  
11 actually wanting to reign in or lower those rates?

12       MS. BRECKENRIDGE: Objection, form.

13       A. Medicaid is always a balance of providing  
14 rates that are high enough to get providers to  
15 participate while at the same time trying to control  
16 a limited budget.

17       Q. (By Ms. O'Sullivan) Was that your  
18 experience the whole time you were the Medicaid  
19 bureau chief?

20       A. And continues to this day.

21       Q. You can put that legislative audit away,  
22 I'm not going to ask you questions about every page

4/12/2006 DALTON, Mary V.1

1 that?

2 A. Pharmacy program officer.

3 Q. Were you consulted prior to the filing of  
4 this lawsuit by the state of Montana?

5 A. When was the lawsuit filed?

6 Q. February 23rd, 2002?

7 A. Not that I recall.

8 Q. When do you recall first learning about  
9 the suit?

10 A. I don't recall the date that I first  
11 learned about it. I'm sure that it probably was--  
12 well, I--I don't know how I--I first heard about it.

13 Q. When you say you don't recall the date, do  
14 you recall the year?

15 A. No.

16 Q. When were you first instructed to preserve  
17 documents relative to the lawsuit?

18 A. I don't know.

19 Q. Do you know when you were first instructed  
20 to preserve e-mails or other electronic documents  
21 relevant to the suit?

22 A. I don't.

# **EXHIBIT 8**



4/11/2006 ELLERY, Nancy V.1

0001

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

-----x

**IN RE: PHARMACEUTICAL INDUSTRY )  
AVERAGE WHOLESALE PRICE LITIGATION,) MDL DOCKET  
-----x CIVIL ACTION**

**THIS DOCUMENT RELATES TO: ) 01CV12257-PBS  
ALL ACTIONS )**

-----x

**DEPOSITION OF NANCY ELLERY**

**April 11, 2006**

**9:14 a.m.**

**Held at:**

**Hampton Inn & Suites**

**155 Southwest Peacock Boulevard**

**Port St. Lucie, Florida**

**Reporter: Tamra K. Piderit, RPR, CRR**

4/11/2006 ELLERY, Nancy V.1

1 Q. And that's the only case in which you have  
2 testified at trial?

3 A. The only one that I can recall.

4 Q. Ms. Ellery, when did you first find out  
5 about this lawsuit?

6 A. I think the first time I found out was  
7 when I got a call from the law firm representing the  
8 State.

9 Q. That was within the last several months?

10 A. Yes.

11 Q. Have you seen a Complaint that describes  
12 the allegations in this case?

13 A. I looked at the original Complaint online.

14 Q. When did you look at the original  
15 Complaint?

16 A. When I first heard about this lawsuit.

17 Q. Could you describe in your own words in  
18 general what the allegations are in the Complaint?

19 A. The allegations are that, you know, the  
20 drug manufacturers have inflated their price that  
21 the State pays.

22 Q. Do you believe that the drug manufacturers

4/11/2006 ELLERY, Nancy V.1

1     **setting up the panel of pharmacies that participated**  
2     **in the Montana Medicaid pharmacy program?**

3         **A. Explain what you mean by panel of**  
4     **pharmacists.**

5         **Q. There were pharmacies that would -- let me**  
6     **start over. There were pharmacies that would**  
7     **provide pharmaceuticals to Montana Medicaid**  
8     **recipients; is that correct?**

9         **A. Yes.**

10        **Q. And were there pharmacies also that did**  
11     **not participate in the Montana Medicaid program?**

12        **A. Yes.**

13        **Q. Were you involved in putting together the**  
14     **group of pharmacies that did participate in the**  
15     **Montana Medicaid pharmacy program?**

16        **A. No.**

17        **Q. Was that done before the time that you**  
18     **became administrator of Montana Medicaid?**

19        **A. Each pharmacy decides on its own when to**  
20     **enroll in the program. I don't have any control**  
21     **over that. I didn't have any control over that.**

22        **Q. Did you see it as part of your job to**

4/11/2006 ELLERY, Nancy V.1

1     **assure that there were a sufficient number of**  
2     **pharmacies participating in the Montana Medicaid**  
3     **program?**

4         **A. Yes, that's part of providing access to**  
5     **care.**

6         **Q. What sort of things did you consider in**  
7     **making the determination that there was or was not**  
8     **sufficient participation by Montana pharmacies in**  
9     **the Montana Medicaid program?**

10        **A. One would be that there are adequate**  
11    **numbers of pharmacies within a reasonable distance**  
12    **of the consumer, the beneficiary.**

13        **Q. Does Montana by virtue of its demographics**  
14    **present any unique challenges with regard to**  
15    **assuring that a sufficient number of pharmacies**  
16    **participate in the Medicaid program?**

17        **A. Yes.**

18        **Q. What are those?**

19        **A. Well, obviously there is much of Montana**  
20    **that is rural that may not have as many providers as**  
21    **the more urban areas. That's a challenge in every**  
22    **service that you provide in Medicaid.**

4/11/2006 ELLERY, Nancy V.1

1       **Q. And how did having rural counties affect -**  
2       **- let me start over. How did having rural counties**  
3       **with only a single or a few pharmacies affect**  
4       **decisions that Montana Medicaid made about**  
5       **reimbursement levels that it would provide to**  
6       **pharmacies that participated in the Montana Medicaid**  
7       **program?**

8       **A. Could you repeat that?**

9       **MR. EVERETT: Maybe the court reporter**  
10       **could read it back.**

11       **(Question read)**

12       **A. You had to consider access to meet the**  
13       **federal regulations that services be available**  
14       **comparable to those that the non-Medicaid population**  
15       **can receive.**

16       **Q. Was there a single reimbursement**  
17       **methodology that was applied to reimbursement for**  
18       **all pharmaceutical products reimbursed by Montana**  
19       **Medicaid?**

20       **A. That was some time ago. I think that we**  
21       **may have at that time had a "lower of" policy, which**  
22       **means that we would pay the lower of the provider's**

4/11/2006 ELLERY, Nancy V.1

1 Q. Can you read the title, though?

2 A. "Licensed Community Pharmacies by County."

3 Q. And part of your role as administrator of  
4 the Medicaid program in Montana was to assure that  
5 pharmacies were available for Medicaid recipients in  
6 as many of the counties as possible; is that  
7 correct?

8 A. We could not generate pharmacies if they  
9 weren't there. We were concerned if there weren't  
10 enough pharmacies, but we didn't have control over  
11 who came into the program.

12 Q. Did you try to set reimbursement for  
13 pharmaceuticals at a level that would assure that  
14 there were pharmacies available for Montana Medicaid  
15 recipients in as many of the counties in Montana as  
16 possible?

17 MR. GAUDET: Objection.

18 A. That's part of what you do when you set  
19 reimbursement is to try to be sure that your  
20 reimbursement rates will allow for access similar to  
21 the private pay population. That's what we do in  
22 every service in Medicaid. It's not possible in all

4/11/2006 ELLERY, Nancy V.1

1 cases, but that's the overall goal.

2 Q. And if you believed that pharmacies in  
3 counties where there were relatively few pharmacies  
4 would leave the Montana Medicaid program if  
5 reimbursements were lowered, would that affect your  
6 decision about reimbursement levels?

7 MR. GAUDET: Objection.

8 A. Would you repeat the question.

9 MR. EVERETT: Would the court reporter  
10 read it back, please.

11 (Question read)

12 A. We had to set reimbursement that would  
13 meet the needs of most of the population. Montana  
14 is a rural state, you cannot generate pharmacies.  
15 So, you know, you took it in consideration, but you  
16 didn't have direct control over it.

17 Q. Did you expect that the pharmacies that  
18 participated in the Montana Medicaid program earned  
19 some profit on sales of pharmaceutical products that  
20 they sold to Montana Medicaid recipients?

21 A. The pharmacies?

22 MR. GAUDET: Objection.

4/11/2006 ELLERY, Nancy V.1

1 Q. How did they require it?

2 A. I take that back. They didn't report it  
3 to the State. I think how it worked was they  
4 reported it through a third-party organization, kind  
5 of self-reported prices, and we got those through  
6 the First Databank. I think that's how it worked.

7 Q. So Montana Medicaid received information  
8 about AWP from third-party sources like First  
9 Databank or Red Book; is that right?

10 A. Right.

11 Q. What did the State of Montana do with that  
12 information?

13 A. We used that to set our reimbursement  
14 level.

15 Q. Did the State of Montana ever require  
16 pharmacies to report their acquisition cost for  
17 drugs?

18 A. I don't recall. I don't know. I can't  
19 remember.

20 Q. Is that something that the State of  
21 Montana could have required?

22 A. To require to do what?



4/11/2006 ELLERY, Nancy V.1

1 Q. You don't remember it at all?

2 A. I know we did it, but I couldn't tell you  
3 when exactly it was.

4 Q. Are there particular states that you would  
5 benchmark for Montana Medicaid?

6 A. Not that I'm aware of. Again, as the  
7 director, you know, that was all done at levels much  
8 lower than I was involved in.

9 Q. But you were involved in setting the  
10 policy for Montana Medicaid, weren't you?

11 A. I was responsible as administrator for the  
12 policy, but staff did all the work and research.

13 Q. If the dispensing fee for pharmaceutical  
14 products were to change, would you have been  
15 involved in that decision?

16 A. Yes.

17 Q. And, likewise, if the reimbursement rate  
18 paid for the ingredient costs of a pharmaceutical  
19 product were changed, you would have been involved  
20 in that decision; is that right?

21 MR. GAUDET: Objection.

22 A. No, not at that kind of detail. I would

4/11/2006 ELLERY, Nancy V.1

1       A. Let me just read it real quick.

2       Q. Sure.

3       A. (Witness reviews document)

4             It does appear to be a response to that.

5       Q. Do you recall whether you discussed this  
6 response with Ms. Poulsen before she sent it to Kim  
7 Johnson?

8       A. I don't recall.

9       Q. Is that something you normally would have  
10 done in the ordinary course of your business?

11       A. It depends on what was going on at the  
12 time. If I was busy with other crises, no, I  
13 wouldn't have discussed it with her, because I  
14 trusted my staff to do the right thing.

15       Q. Does the fact that you were copied on this  
16 memo suggest to you that you discussed the response  
17 with Ms. Poulsen before it was sent?

18             MR. GAUDET: Objection.

19       A. Not necessarily. She would -- since the  
20 original thing was addressed to the Medicaid  
21 director, she would have out of protocol copied me  
22 on the response. That doesn't mean we talked about

4/11/2006 ELLERY, Nancy V.1

1           **MR. GAUDET: Objection.**

2           **A. No.**

3           **Q. Are you aware of any other criticisms that**  
4           **Montana Medicaid had with regard to the 1996 OIG**  
5           **report?**

6           **A. No.**

7           **Q. For most pharmacy issues were you**  
8           **comfortable relying on the expertise of your staff**  
9           **in making decisions?**

10          **A. Yes.**

11          **Q. Did you have any reason to believe --**  
12          **strike that.**

13               **Did you have any reason to doubt work done**  
14          **by Terry Krantz relating to the 1996 OIG report?**

15          **A. No.**

16          **Q. In general you felt comfortable relying on**  
17          **Mr. Krantz?**

18          **A. Actually, Jeff Ireland was the pharmacy**  
19          **manager, so he was the primary one involved.**

20          **Q. Would you feel comfortable relying in**  
21          **general on Mr. Ireland?**

22          **A. Yes.**

4/11/2006 ELLERY, Nancy V.1

1 Q. Do you know who Michael S. Billings is?

2 A. Yes.

3 Q. Who is he?

4 A. He at the time was administrator of the  
5 Operations and Technology Division in the  
6 department. He obviously was acting on behalf of  
7 Mr. Blouke and signing the letter.

8 Q. In general in evaluating the reimbursement  
9 methodology utilized by Montana Medicaid for  
10 pharmacy products, did Montana Medicaid consider it  
11 important to consider both the ingredient cost and  
12 the dispensing fee together?

13 MR. GAUDET: Objection. Foundation.

14 A. Would you repeat the question?

15 (Question read)

16 A. I don't recall.

17 Q. Do you recall any discussions during your  
18 time as director of Montana Medicaid about the  
19 dispensing fee that was paid to pharmacists who  
20 dispensed pharmacy products to recipients?

21 MR. GAUDET: Objection.

22 A. Yes.

4/11/2006 ELLERY, Nancy V.1

1 Q. What discussions do you recall?

2 A. That the dispensing fee was not adequate  
3 to cover their cost.

4 Q. And what was the basis for the belief of  
5 Montana Medicaid that the dispensing fee was  
6 inadequate to cover the costs of pharmacies?

7 A. This is what the pharmacies told us. At  
8 some point in this process we had a survey of the  
9 dispensing fees to validate or not validate what  
10 they were telling us.

11 Q. Was the inadequate dispensing fee  
12 subsidized by the ingredient cost of the  
13 reimbursement?

14 A. I don't know. I don't recall.

15 Q. Did Montana Medicaid change the dispensing  
16 fee during your time as director of the Montana  
17 Medicaid program to make it adequate?

18 A. I think we did. I can't tell you when. I  
19 know we did something as a result of the dispensing  
20 fee survey, but I don't know when that was.

21 Q. Let's turn back to the beginning of  
22 Exhibit Ellery 012. Take a look at the first

4/11/2006 ELLERY, Nancy V.1

1 paragraph of page 19235, under the heading  
2 "Introduction." Does that refresh your recollection  
3 at all as to Montana Medicaid's participation in a  
4 survey of acquisition costs that was then reported  
5 in the 1996 OIG report?

6 A. It just tells me that HCFA requested them  
7 to take a look at this, but I don't recall the  
8 details of that.

9 Q. Do you recall that Montana Medicaid did,  
10 in fact, do that?

11 A. Yes. When CMS requests you to do  
12 something, you do it.

13 Q. If you look at the last sentence under the  
14 first paragraph under the heading "Background," it  
15 says, "The State agencies are responsible for  
16 determining the EAC and the dispensing fee."

17 Do you see that?

18 A. Yes.

19 Q. Does that accurately reflect your  
20 understanding of the State agency's responsibility  
21 with regard to EAC and dispensing fees?

22 A. At that time it did.

4/11/2006 ELLERY, Nancy V.1

1 companies that publish the prices in the Red Book  
2 and First Databank.

3 Q. Did you believe that it reflected the  
4 actual acquisition costs of pharmacies?

5 A. No, because that's why we had a discount  
6 off of it.

7 Q. Did you believe that there was a standard  
8 and consistent difference between the acquisition  
9 cost of pharmacies and the published AWP?

10 MR. GAUDET: Objection.

11 A. I don't recall.

12 Q. Did you believe that AWP reflected  
13 acquisition costs for physicians?

14 A. I don't know.

15 Q. Did you believe that AWP reflected  
16 acquisition costs for hospitals?

17 A. I don't know.

18 Q. If you turn to page MT 19240, the first  
19 full sentence of the second full paragraph under  
20 "Conclusions and Recommendations" says that "We  
21 recognize that acquisition cost is just one factor  
22 in pharmacy reimbursement policy and that any change

4/11/2006 ELLERY, Nancy V.1

1 Dorothy Poulsen was the pharmacy manager for a  
2 significant portion of your tenure; is that correct?

3 A. That's not what I said. Dorothy was the  
4 program manager at the time that I left.

5 Q. Okay.

6 A. I don't recall how long she was the  
7 manager, but she was the pharmacy manager at the  
8 time that I left.

9 Q. As the pharmacy manager she would be the  
10 person most knowledgeable about pharmacy related  
11 issues?

12 A. Absolutely.

13 Q. I'm going to read you a section of the  
14 deposition transcript from Ms. Poulsen's February  
15 22nd transcript.

16 A. Okay.

17 Q. "I wanted to make sure that we had access  
18 to the drugs needed by our client. We have three  
19 constituency in that position; you have the client,  
20 the providers with whom you want to have a good  
21 relationship and cooperative relationship, and you  
22 have the taxpayer. You have a responsibility, you



4/11/2006 ELLERY, Nancy V.1

1 are the State, in balancing those three roles was  
2 always what it was you tried to do."

3 Do you agree with that statement?

4 A. Yes.

5 Q. Do you have anything to add to that  
6 statement?

7 A. It was well stated.

8 MS. NEMIROW: I have nothing further.

9 MR. CLARK: No questions.

10  
11 CROSS EXAMINATION

12 BY MR. KATZ:

13 Q. My name is Clifford Katz, and I represent  
14 Dey. Have you heard of the pharmaceutical company  
15 called Dey?

16 A. No.

17 Q. Ms. Ellery?

18 A. No. I'm sorry, I will get closer to the  
19 phone. I have not heard of that company.

20 Q. So is it safe to say you have never had  
21 any communications with any representatives of Dey?

22 A. That's correct.

# **EXHIBIT 9**

4/18/2006 HUNTER, Charles L. V.1

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1                   **THE UNITED STATES DISTRICT COURT**  
2                   **FOR THE DISTRICT OF MASSACHUSETTS**

3                   **---000---**

4                   **-----X**

5           **In Re: PHARMACEUTICAL        ) MDL DOCKET NO.**  
6           **INDUSTRY AVERAGE WHOLESALE   ) CIVIL ACTION**  
7           **PRICE LITIGATION                ) 01CV12257-PBS**

8                   **-----X**

9           **THIS DOCUMENT RELATES TO:    )**  
10           **ALL ACTIONS                        )**

11                   **-----X**

12                   **TELEPHONE DEPOSITION**  
13                   **OF**  
14                   **CHARLES L. HUNTER**

15  
16                   **Taken at 33 South Last Chance Gulch**  
17                   **Helena, Montana**  
18                   **Tuesday, April 18, 2006 - 9:50 a.m.**

19  
20                   **Reported by Mary R. Sullivan, RPR, RMR, Freeland**  
21                   **Court Reporter, Notary Public, residing in Missoula,**  
22                   **Montana.**

4/18/2006 HUNTER, Charles L. V.1

1 Q. Did this initiative ultimately get  
2 implemented?

3 A. In a much smaller way than originally  
4 thought. It turned out that only the hospitals were  
5 a group that wanted to be involved in this.

6 Q. And why was that?

7 MS. BRECKENRIDGE: Objection.

8 A. If you're familiar with how provider tax  
9 works, you have to have all providers in a  
10 particular service type and you have to tax every  
11 one of them, you have to tax them equally. The  
12 hospitals were the only group that was cohesive  
13 enough with a clear enough direct benefit to them  
14 with enough experience, you know, where they looked  
15 at other states and saw how this worked, that it  
16 made sense for them to step up to the plate and say,  
17 yeah, we want to do this. There were other groups  
18 that would have benefited, but they were the only  
19 ones that saw the benefit and didn't have the fear  
20 of it, and, thus, acted on it.

21 Q. (By Mr. Baranski) Okay. You mentioned  
22 access as part of this initiative. Can you explain

4/18/2006 HUNTER, Charles L. V.1

1 what you mean by access generally?

2 A. What I mean by that is having enough  
3 providers who are willing to be part of the Medicaid  
4 network to assure Medicaid clients of being able to  
5 go to the types of service providers they need.

6 Q. And does Montana's rural and frontier  
7 nature provide specific access challenges to the  
8 state?

9 A. Yes.

10 Q. What are those?

11 A. The challenges are, you know, pretty  
12 simply stated, in a couple of ways. One is, you  
13 know, lots of square miles, not many people. There  
14 are not many physicians or other medical specialists  
15 out in those communities. Travel is the other  
16 issue, people have to travel a long way. It's kind  
17 of the flip side of the answer I just gave you.

18 Q. And providers' participation in the  
19 Medicaid program is voluntary, correct?

20 A. Correct.

21 Q. And are they free to leave the program at  
22 any time that they choose to or--

4/18/2006 HUNTER, Charles L. V.1

1 A. Yes.

2 Q. Would the access issues that you just  
3 discussed generally that arise from Montana's sort  
4 of makeup, would those access concerns apply to  
5 pharmacies, for instance?

6 A. Yes.

7 Q. And what about physicians who see patients  
8 in their offices and administer physician  
9 administered drugs?

10 A. Yes.

11 Q. And one of the ways that the State has to  
12 deal with the access challenges is ensuring adequate  
13 reimbursement to these providers, correct?

14 A. Correct.

15 MS. BRECKENRIDGE: Objection.

16 Q. (By Mr. Baranski) Other than this  
17 Medicaid assessment initiative that you worked on in  
18 2002, for that job position, because I know you said  
19 you switched about a year later, were there any  
20 other Medicaid initiatives that you worked on during  
21 that 2002 time period that related to Medicaid's  
22 coverage of prescription drugs?

4/18/2006 HUNTER, Charles L. V.1

1 for documents related to this lawsuit?

2 A. No.

3 Q. Did you delegate to anyone to have them do  
4 a search?

5 A. There was a discussion at the meeting that  
6 I mentioned prior about where those documents--where  
7 documents related to this lawsuit might exist, and  
8 it was generally agreed that those documents existed  
9 at lower levels than mine, and that Duane Preshinger  
10 and his staff were the place where those documents  
11 would reside, so it was agreed that's where the  
12 document search would take place.

13 Q. And that--that meeting took place in the  
14 summer of 2005?

15 A. That's my recollection of it.

16 Q. And you don't--do you recall any other  
17 meetings related to this lawsuit that you attended?

18 A. No.

19 Q. Had you heard of the lawsuit prior to that  
20 meeting?

21 A. Briefly. I hadn't heard a lot about it.

22 Q. Were you consulted in any way prior to the

4/18/2006 HUNTER, Charles L. V.1

1 filing of the lawsuit?

2 A. No.

3 Q. Did you receive any instruction about the  
4 need to retain documents because of this lawsuit?

5 A. No.

6 Q. When you first became involved in 2002,  
7 July of 2002 with the Medicaid program, do you  
8 recall inheriting any files from anyone?

9 A. There were all the files from the former  
10 administrator there that related to Medicaid.

11 Q. And who was the former administrator?

12 A. Nancy Ellery actually, and Maggie Bullock  
13 was my direct predecessor. There were files from  
14 both those people in my office.

15 Q. Did you ever look through those files in  
16 connection with your work responsibilities?

17 A. Not really. I did retain those files for  
18 a period of time just to see if I would need them.  
19 There were files that I kept in the office for about  
20 six months, didn't find that I was in those files,  
21 so they were moved to storage.

22 Q. What happened with your files when you



4/18/2006 HUNTER, Charles L. V.1

1 less 15 percent to AWP less 25 percent. Did you  
2 have any involvement in this proposal?

3 A. No.

4 Q. Do you have any recollection of this  
5 proposed change?

6 A. No.

7 Q. Did you ever have any communications with  
8 providers regarding the proposed change to go from  
9 AWP minus 15 percent to AWP minus 25 percent?

10 A. Nope.

11 EXHIBIT:

12 (Exhibit Hunter 005 marked for  
13 identification.)

14 Q. (By Mr. Baranski) Mr. Hunter, the  
15 document I've put before you is a 2002 survey of  
16 Montana community pharmacies Bates labeled MT 025491  
17 through MT 025510. Do you recognize this document?

18 A. No.

19 Q. Never seen it before, huh?

20 A. Nope.

21 Q. Do you have any understanding of what some  
22 of the unique concerns that rural pharmacies in

4/18/2006 HUNTER, Charles L. V.1

1 Montana have with respect to Medicaid reimbursement?

2 MS. BRECKENRIDGE: Objection, form.

3 A. I have heard it said that they're  
4 concerned about several things. They're concerned  
5 about having access to Medicaid reimbursement  
6 because Medicaid can provide a foundation for  
7 businesses to stay open. I have heard it said that  
8 there's concern about reimbursement level because if  
9 reimbursement isn't adequate, it makes it difficult  
10 for them to provide service or to keep their doors  
11 open in rural communities. I have heard that rural  
12 pharmacies like Medicaid because Medicaid is a good  
13 payer in comparison to others. I have heard that  
14 rural pharmacies don't like Medicaid because  
15 Medicaid is not a good payer in comparison to  
16 others, so those kind of sum up the things I've  
17 heard about rural pharmacy issues related to  
18 Medicaid.

19 Q. (By Mr. Baranski) Is insuring beneficiary  
20 access to pharmacies participating in the Medicaid  
21 program for rural beneficiaries a concern faced by  
22 the Montana Medicaid program?

4/18/2006 HUNTER, Charles L. V.1

1 A. Yes.

2 Q. And how does the Medicaid program address  
3 that concern?

4 A. Well, trying to make sure that to the  
5 extent that there are rural pharmacies, that  
6 reimbursement is enough so that rural pharmacies  
7 will continue to provide Medicaid scripts. I will  
8 also tell you that, you know, there--there is some  
9 recognition that going to mail order pharmacy would  
10 be a cheaper way to go and would provide access to,  
11 you know, rural constituents.

12 Q. But why hasn't the Medicaid program--

13 A. Purely political. I mean--

14 Q. Can you explain it, please?

15 A. You want to keep main street businesses  
16 open.

17 Q. Do the--to your knowledge, do the  
18 pharmacists lobby the legislature on Medicaid  
19 reimbursement issues?

20 A. Yes.

21 Q. Would you, in your words, describe the  
22 Montana pharmacies as a powerful lobbying entity?

## **EXHIBIT 10**

4/10/2006 IRELAND, Jeffrey E. V.1

1           **THE UNITED STATES DISTRICT COURT**  
2           **FOR THE DISTRICT OF MASSACHUSETTS**

3           **---OoO---**

4           **-----X**

5       **In re: PHARMACEUTICAL        ) MDL DOCKET NO.**  
6       **INDUSTRY AVERAGE WHOLESALE   ) CIVIL ACTION**  
7       **PRICE LITIGATION                ) 01CV12257-PBS**

8           **-----X**

9       **THIS DOCUMENT RELATES TO:    )**

10       **ALL ACTIONS                    )**

11       **-----X**

12           **Taken at 33 South Last Chance Gulch**

13           **Helena, Montana**

14           **Monday, April 10, 2006 - 3:00 p.m.**

15  
16           **D E P O S I T I O N**

17           **O F**

18           **JEFFREY E. IRELAND**

19  
20       **Reported by Mary R. Sullivan, RPR, RMR, Freelance**  
21       **Court Reporter and Notary Public, State of Montana,**  
22       **residing in Missoula, Montana.**

4/10/2006 IRELAND, Jeffrey E. V.1

1       probably issued by pharmacies in Montana.

2       Q.   Okay.

3       A.   So given that information, my response  
4       would be yes, that would have been there when I took  
5       over the program.

6       Q.   And was there some perceived benefit of  
7       having rural pharmacy available for Montana  
8       citizens?

9       MS. BRECKENRIDGE: Objection. You can  
10      answer when I object.

11      Q.   (By Mr. Waterman) You can answer.

12      A.   If I remember correctly, our  
13      responsibility was to make sure that access to  
14      pharmaceuticals was made available to eligible  
15      Medicaid recipients. Because of the geographic size  
16      and remoteness of the state of Montana, obviously  
17      every pharmacy that we could have that would  
18      participate would extend access to Medicaid  
19      recipients, so given that information, my response  
20      would be yes, that it was important that we have,  
21      you know, as many pharmacies participate to include  
22      those areas.

4/10/2006 IRELAND, Jeffrey E. V.1

1 Q. Could it be that the survey does not  
2 include claims that have been submitted and paid in  
3 the usual and customary manner?

4 A. I suppose.

5 Q. But, again, you've not really--you don't  
6 have a remembrance of seeing this document.

7 A. No, I don't.

8 Q. Nor providing any comment on it.

9 A. No, I don't, given the information that I  
10 have in front of me.

11 Q. Okay. Do you know what percentage,  
12 roughly, of the Montana Medicaid claims that were  
13 paid and U & C rather than the AWP minus ten  
14 percent?

15 A. No, I don't.

16 Q. Would you go back to the first page? On  
17 the first paragraph, the fourth line, apparently Mr.  
18 Krantz says, "While AWP is a national standard it is  
19 apparent from the results of the survey that it has  
20 little to do with the acquisition costs of pharmacy  
21 products." Do you see that?

22 A. Yes, I do.

4/10/2006 IRELAND, Jeffrey E. V.1

1 Q. Was that your understanding at the time as  
2 well?

3 A. Yes.

4 Q. Okay.

5 MR. WATERMAN: It's about 20 of five.  
6 We've been going for about an hour and 20 minutes.  
7 Do you want to take a break?

8 THE COURT REPORTER: I'm fine.

9 MR. WATERMAN: Does anybody want to take a  
10 break?

11 A. No, I'm okay.

12 EXHIBIT:

13 (Exhibit Ireland 005 marked for  
14 identification.)

15 Q. (By Mr. Waterman) Showing you Deposition  
16 Exhibit Ireland 005, take a moment to look through  
17 that, please.

18 A. Okay.

19 Q. The issue of pharmacy acquisition costs  
20 would have been one of the issues that you were  
21 dealing with as the PPM for Medicaid back in 1996;  
22 is that correct?



4/10/2006 IRELAND, Jeffrey E. V.1

1       whether or not they should, and if so, what is your  
2       memory of that discussion?

3           A.    I don't remember any specific, you know,  
4       discussion as a result of that report.

5           Q.    The same would be true with respect to  
6       changing the standards so that it was more closely  
7       tied to the actual acquisition costs. I take it you  
8       don't remember any discussions about that either.

9           A.    No, I don't.

10          Q.    Did the State at that time in 1996 have  
11       the power to design its own Medicaid drug  
12       reimbursement program?

13          A.    The State had flexibility to determine the  
14       reimbursement, but I believe that there were federal  
15       guidelines that we had to, you know, follow, so,  
16       yes, there was flexibility for the State to have,  
17       you know, specific things that may be unique to the  
18       State itself.

19          Q.    Okay. And if the State had wanted to  
20       reimburse pharmacies for actual acquisition costs,  
21       it could have done so, couldn't it?

22          A.    Without, you know, specific information

4/10/2006 IRELAND, Jeffrey E. V.1

1 and having the references as far as the guidelines,  
2 I don't know if I can answer yes or no, you know, to  
3 that question.

4 Q. Would it be correct that they could have  
5 done so? At least your knowledge is they could have  
6 done so to the extent that the guidelines or  
7 regulations permitted.

8 A. My understanding, that's correct.

9 Q. Okay. Do you know of any instance where a  
10 Medicaid provider provided Montana Medicaid with  
11 actual retail pricing data?

12 A. Actual retail pricing data. Meaning the  
13 costs that they would charge any paying customer?

14 Q. Uh-huh.

15 A. Well, they gave it to us when they billed  
16 us, so if they billed us with the amount that they  
17 actually charged, we would get that data all the  
18 time.

19 Q. Do you know whether or not that is, in  
20 fact, what they gave you?

21 A. No, we don't. In some instances, you'd  
22 have to make the assumption, you know, without going

4/10/2006 IRELAND, Jeffrey E. V.1

1 don't know that I would be able to tell you whether  
2 my response would have been different because I  
3 don't know what the HMO had to offer, but one of the  
4 things that had to be considered was that currently  
5 we're receiving a rebate that offsets our  
6 pharmaceutical costs, and that needed to be  
7 considered in this particular type of an approach.

8 Q. (By Mr. Waterman) On the second page at  
9 the very bottom talking about reimbursement changes,  
10 you say--it looks like the second sentence, "The AWP  
11 was based upon a standard package size of 100 units  
12 or 480 millimeters. This was used regardless of the  
13 actual AWP of the product being dispensed." The--  
14 when you say actual AWP, you mean the actual or the  
15 AWP published in First Data Bank?

16 A. Yes, that would be where we would have  
17 gotten all of our AWP information.

18 Q. Okay. Does that mean that the AWP  
19 published in the First Data Bank might have been  
20 higher or lower than Montana Medicaid actually paid,  
21 the amount that Montana Medicaid actually paid?

22 MS. BRECKENRIDGE: Objection.

4/10/2006 IRELAND, Jeffrey E. V.1

1 or did you do everything in the first instance  
2 related to pharmacy?

3 A. I think it would be a fair statement to  
4 say that he did have some involvement with me as a  
5 program officer. Initially it was a pretty big  
6 program, and to start with, there may have been  
7 things that he was involved with that he carried on,  
8 but I was always kept involved in most instances or  
9 at least understood what was going on. Maybe I  
10 didn't have the in-depth knowledge that I would have  
11 had I done the project myself.

12 Q. I think in the correspondence he's  
13 designated by people within the Montana Medicaid  
14 program as the point of contact for the OIG in that  
15 study and that's what prompted that question.

16 A. Uh-huh.

17 Q. Given that as I--as I understand it, you  
18 don't recall much of anything related to that study.

19 A. Right.

20 Q. You indicated earlier that your AWP data  
21 came from either Medispan or Blue Book or Red Book.  
22 Do you recall specifically which outfit you got it

4/10/2006 IRELAND, Jeffrey E. V.1

1 from and how?

2 A. Let me think. I believe that Red Book  
3 sticks in my mind.

4 Q. First Data Bank?

5 A. First Data Bank, and I believe that they  
6 were the ones that we used through MMIS that  
7 actually used the reimbursement, but when we had the  
8 contract with Pharmark, I believe they used  
9 Medispan.

10 Q. And when you refer to Pharmark, what is  
11 Pharmark?

12 A. Pharmark was the contract that we let for  
13 the Drug Utilization Review program, and the Montana  
14 Wyoming Foundation was subcontracted by them to  
15 perform that because we required an entity located  
16 here in Helena, so that's what that is. I don't  
17 know who they're called now or if they're still  
18 around.

19 Q. Was the contract between First Data Bank  
20 and I think you said MMIS?

21 A. Well, the MMIS is the Medicaid Management  
22 Information System that was run by Consultec who was

4/10/2006 IRELAND, Jeffrey E. V.1

1 average wholesale price?

2 A. I don't.

3 Q. Are you aware of any guidance that the  
4 Montana Medicaid program provides to manufacturers  
5 regarding what average wholesale price is supposed  
6 to represent?

7 A. No.

8 Q. I apologize in advance because I'm sure  
9 I'm going to confuse what you said even more than--

10 A. Sure.

11 Q. --I--

12 A. It's a challenge.

13 Q. --but earlier you were asked a series of  
14 questions about how you obtained--prior to 1994 the  
15 State obtained AWP information and somehow converted  
16 it to different package sizes for reimbursement.

17 A. Uh-huh.

18 Q. And then in 1994 changed back to just  
19 using whatever FDB published its AWP.

20 A. Right.

21 Q. Is it fair to say that prior to 1994 you--  
22 the Montana Medicaid program or Consultec on your

# **EXHIBIT 11**

Terry Krantz

March 17, 2006

Helena, MT

1

THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

**CERTIFIED COPY**

-----  
)  
)  
IN RE: PHARMACEUTICAL )  
INDUSTRY AVERAGE )  
WHOLESALE PRICE )  
LITIGATION, ) Civil Action 01CV12257PBS  
)  
-----

DEPOSITION UPON ORAL EXAMINATION OF  
TERRY KRANTZ  
-----

8:30 a.m.

March 17, 2006

GOUGH SHANAHAN JOHNSON & WATERMAN

33 South Last Chance Gulch

Helena, Montana 59601

REPORTED BY: Judith A. Robinson, CCR #2171

Henderson Legal Services  
(202) 220-4158



Terry Krantz

March 17, 2006

Helena, MT

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1 by, "no information has been developed"?

2 **A. No.**

3 Q. Looking at the second page of Exhibit  
4 Krantz 002 -- I'm sorry. I went ahead of myself.

5 Below the average wholesale price review  
6 on the first page of Exhibit Krantz 002 is something  
7 that says, "Mail Order Drugs." Do you see that?

8 **A. Yes.**

9 Q. And did you write, "It is the consensus of  
10 the States that this will not be cost effective  
11 because of on- and-off nature of eligibility, the  
12 waste involved to guarantee the delivery of the  
13 drugs, the economic impact on some rural retail  
14 pharmacies." And then you stated other reasons.

15 Do you remember what you meant by,  
16 "talking about the economic impact on some rural  
17 retail pharmacies"?

18 **A. My recollection is that it was the**  
19 **consensus of the states that small rural retail**  
20 **pharmacies would suffer a loss of business if we**  
21 **moved towards mail-order drugs.**

22 Q. Was that also a consensus of Montana

Terry Krantz

March 17, 2006

Helena, MT

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1 Medicaid?

2           **A. At that time I -- I don't recall. I don't**  
3 **recall if it was a finish if Montana was in the**  
4 **consensus or not.**

5           Q. While you worked at Montana Medicaid in  
6 pharmacy issues, was the viability of Montana's  
7 rural pharmacies a concern for you?

8           **A. Yes.**

9           Q. Why was that?

10          **A. Access to services was always a concern.**

11          Q. Now looking at page 2 of Exhibit Krantz  
12 002, there's some handwriting at the end.

13               Do you recognize that?

14          **A. No, I don't.**

15          Q. I would like you to look at Exhibit Krantz  
16 003 which is entitled, "Partnership Plan,  
17 Federal/State Joint Audits of the Medicaid Program."

18               Would you please look at this document and  
19 tell me if this was the Federal/State Joint Audits  
20 that you were referring to in your memo that's  
21 Exhibit Krantz 002?

22          **A. Yes. It appears to be the document.**

Terry Krantz

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1 paragraph, third sentence that starts, "In Montana."

2 Do you see that? Page 2 of Exhibit Krantz  
3 004, first full paragraph, third sentence, "In  
4 Montana."

5 A. Yes.

6 Q. Where you wrote, "In Montana we currently  
7 have a fairly good idea that the dispensing fee  
8 reimbursed is below the cost to dispense because of  
9 the cap on dispensing fees that is currently in  
10 place," do you recall your basis for saying that the  
11 dispensing fee reimbursed is below the cost to  
12 dispense?

13 A. I believe I stated it in the response that  
14 we had a cap on the dispensing fees at that point in  
15 time and as costs rise, the cap kept the dispensing  
16 fee below the actual cost to dispense. That is what  
17 led to this statement.

18 Q. So you knew, at least as of writing this  
19 memo in 1995, that a provider would lose money on  
20 every transaction if they were reimbursed at their  
21 actual acquisition cost?

22 A. I -- the statement was made that we had a

Terry Krantz

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Helena, MT

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1 fairly good idea that the dispensing fees were  
2 actually being reimbursed at below cost. But we  
3 didn't have any specific information as to what that  
4 amount might be.

5 Q. Have you ever seen pharmacy dispensing fee  
6 surveys filled out by Montana Medicaid providers?

7 A. Yes. I believe we -- I have seen them,  
8 yes.

9 Q. And in those dispensing fee surveys, were  
10 providers required to provide data about their cost  
11 to dispense drugs?

12 A. I don't recall specifically.

13 Q. What do you recall was contained in those  
14 dispensing fee surveys?

15 A. I just recall that we used to do  
16 dispensing fee surveys.

17 Q. When you were the supervisor over the  
18 pharmacy program, do you remember who was the person  
19 who was responsible for the dispensing fee surveys?

20 A. I believe it was the pharmacy program  
21 officer.

22 Q. Looking at page 2 of Exhibit Krantz 004,

Terry Krantz

March 17, 2006

Helena, MT

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1           **A.    Yes.**

2           Q.    Do you believe you received a copy of this  
3           letter that's the last two pages of Exhibit Krantz  
4           006?

5           **A.    Yes.**

6           Q.    The last page of Mr. Blouke's letter  
7           signed by Mr. Billings states:

8                     "If you have any questions, please contact  
9           Terry Krantz of my staff."

10                    Is it fair to say, you were the point  
11           person for Montana Medicaid on the OIG's '96 report?

12           **A.    Yes.**

13           Q.    The other people listed as CCs are, Mary  
14           Dalton, Nancy Ellery and Jeff Ireland; correct?

15           **A.    Yes.**

16           Q.    Was each of them also involved in the OIG  
17           study?

18           **A.    I'm not sure how to answer that. I assume**  
19           **that they would have been involved in at least to**  
20           **the level of being kept aware of what was occurring.**

21           Q.    Can you recall specifically as to any of  
22           them individually what their role was with the OIG

Terry Krantz

March 17, 2006

Helena, MT

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1 report?

2 A. No.

3 Q. If you could pull back out Exhibit Krantz  
4 004 and also keep in front of you the last two pages  
5 of Exhibit Krantz 006?

6 A. Okay.

7 Q. So Exhibit Krantz 004 was your memo of  
8 October 5, 1995 to Nancy Ellery; right?

9 A. Yes.

10 Q. And I'd like you to look from your memo  
11 starting, "It is important to note." That  
12 paragraph.

13 A. Okay.

14 Q. And then looking at the last two pages of  
15 Exhibit Krantz 006, the Mr. Blouke letter signed by  
16 Mr. Billings, starting with the second paragraph,  
17 "It is important to note."

18 Can you just take a look at those two  
19 exhibits in conjunction with each other?

20 A. Okay.

21 Q. Is it fair to say, that the letter on  
22 behalf of Mr. Blouke from April 1996 was based

Terry Krantz

March 17, 2006

Helena, MT

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1 of acquisition costs without a discount off of AWP  
2 being applied.

3 BY MS. O'SULLIVAN:

4 Q. Going back to Exhibit Krantz 006 for just  
5 a minute. The final report of the OIG relating to  
6 Montana Medicaid from 1996.

7 I believe you testified that you saw --  
8 you saw that report before; correct?

9 A. The Exhibit Krantz 006 report?

10 Q. Yes.

11 A. Yes.

12 Q. Do you remember who else in Montana  
13 Medicaid received that final report?

14 A. I guess I have to assume that all the  
15 people that are listed on the report as being CC'd.  
16 I don't specifically recall who would have received  
17 it but I think we discussed the general routing  
18 practices.

19 Q. It would be your assumption that Nancy  
20 Ellery and Mary Dalton and Jeff Ireland would have  
21 also received a copy of the final report?

22 A. Yes.

Terry Krantz

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Helena, MT

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1 Q. As well as the director of DPHHS, Peter  
2 Blouke?

3 A. Yes.

4 Q. Do you recall any discussions you had with  
5 any of those individuals about what Montana Medicaid  
6 should do, if anything, in response to that report?

7 A. No.

8 Q. Have you ever seen a report like Exhibit  
9 Krantz 006 for any states other than Montana?

10 A. I don't recall seeing any of the other  
11 reports.

12 Q. You were aware they existed?

13 A. I assume they existed. Because there were  
14 11 states involved in the study.

15 Q. Just a few questions before we take a  
16 break.

17 At Montana state, did you ever take any  
18 courses in pharmacy?

19 A. No.

20 Q. After you graduated, did you ever take any  
21 courses in pharmacy?

22 A. No.



Terry Krantz

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Helena, MT

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1           **A.    No.**

2           Q.    Just no recollection at all?

3           **A.    No recollection.**

4           Q.    To your knowledge, did the State of  
5 Montana ever define the term AWP, or average  
6 wholesale price?

7           **A.    If there were a definition of AWP, it**  
8 **would probably be located in the administrative**  
9 **refusals Montana related to the pharmacy program. I**  
10 **can't specifically recall if there's a definition in**  
11 **that rule.**

12          Q.    You're not aware of any such definition?

13          **A.    No.**

14          Q.    To your knowledge, does the State of  
15 Montana require manufacturers to report any sort of  
16 pricing information to the State of Montana?

17               MS. BRECKENRIDGE: Objection.

18          **A.    Could you restate that?**

19       **BY MR. DILLON:**

20          Q.    To your knowledge, does the State of  
21 Montana require pharmaceutical manufacturers to  
22 report any pricing information to the State of

Terry Krantz

March 17, 2006

Helena, MT

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1 BY MR. DILLON:

2 Q. Was the State of Montana interested in  
3 increasing the use of generic versus brand-name  
4 drugs?

5 A. I would say that the State of Montana was  
6 interested in using the least costly alternative  
7 that was appropriate for the situation. That would  
8 be how I would categorize it.

9 Q. Did the State of Montana for their  
10 Medicaid program have a mandatory generic  
11 substitution program?

12 A. I don't specifically recall.

13 Q. Do you recall whether there was a  
14 difference in the co-payment for generic versus  
15 brand-name drugs?

16 A. I don't recall at that time, no.

17 Q. Are you aware of state MAC, maximum  
18 allowable cost, what that term means?

19 A. I have heard the term before. I wouldn't  
20 be able to define it.

21 Q. To your knowledge, did the State of  
22 Montana ever consider for its Medicaid program

Terry Krantz

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Helena, MT

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1 setting up its own MAC program separate than the  
2 federal upper limit program?

3 A. I'm not aware of a State MAC program or  
4 any discussions related to a creation of one.

5 Q. Were you aware that other states had  
6 created such programs?

7 A. Yes.

8 Q. Were you familiar at the time with how  
9 other third-party payers were reimbursing drugs?

10 A. I would say that probably not --

11 Q. At that time --

12 A. -- at that time familiar.

13 Q. Mr. Krantz, a couple more questions. One  
14 is, in your role as supervisor of the acute services  
15 section, was your job -- did your job involve just  
16 implementing policy or were you also involved in the  
17 creation of policy related to those areas?

18 A. I would categorize it as being  
19 recommending policy changes. Most of the policy  
20 changes did have to be approved by either the  
21 Medicaid division administrator or the department  
22 director.